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UNITED STATES DISTRICT COURT

DISTRICT OF OREGON

OREGON MEDICAL ASSOCIATION, an Oregon not for profit corporation; **ANTON K. BROMS, MD**, an individual; and **STEWART M. WILSON, J.R., MD**, an individual.

Plaintiffs,

v.

MICHAEL O. LEAVITT, in his official capacity as Secretary of Health and Human Services; **LESLIE V. NORWALK**, in her official capacity as Acting Administrator of Centers for Medicare and Medicaid Services; **UNITED STATES OF AMERICA**; **UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES;** and **CENTERS FOR MEDICARE AND MEDICAID SERVICES**.

Defendants.

Case No. CV 06-1871 HU

AMENDED COMPLAINT
Declaratory Judgment and Injunctive Relief
(28 U.S.C. § 2201 and 5 U.S.C. § 553)

Nature of Action

1.

Plaintiffs' seek declaratory judgment and injunctive relief to prevent the Centers for Medicare and Medicaid Services (hereinafter "CMS"), and the United States Department of Health and Human Services (hereinafter "HHS") from exceeding their authority and encroaching upon the State of Oregon's police power to regulate the practice of medicine within the borders of Oregon. Defendants have been enforcing against Hospitals an Interpretive Guideline which alters an Oregon State law that specifies what a physician must do to obtain a patient's informed consent for certain medical care. Defendants' definition of patient "informed consent" and what is minimally necessary is contrary to Oregon law, ORS 677.097. This alteration of what Oregon has declared to be the law to be followed by physicians exceeds the authority delegated to the Secretary of Health and Human Services, violates the Social Security Act, and is unconstitutional. The Defendant CMS cite hospitals for not complying with its Informed Consent Guidelines and Hospitals then require physicians affiliated with the Hospitals to comply with Defendant CMS's Informed Consent Guidelines or face termination.

2.

Plaintiffs' Complaint was originally filed when a prior revision of the CMS Interpretive Guidelines for Informed Consent were in effect, and dealt with Hospital Citations that had occurred while the now revoked interpretive guidelines were in effect. Hospitals had been cited under the prior guideline and Hospitals had forced physicians to use Defendant CMS's form of informed consent which was contrary to Oregon law. On April 13, 2007, CMS issued "Revision to the Hospital Interpretive Guidelines for Informed Consent." CMS's revised interpretive

guidelines for informed consent were effective immediately, on April 13, 2007, and revoked the prior version of these guidelines about which Plaintiffs complained. Even though CMS has made revisions to its interpretive guidelines on informed consent, at least one of these guidelines is still contrary to Oregon law and dictates what a physician must minimally do to obtain a patient's informed consent for certain medical care.

Jurisdiction and Venue

3.

This Court has jurisdiction under 28 U.S.C. § 1331 (federal question) and 28 U.S.C. § 1346(a)(2) (civil action against the United States). A declaratory judgment action and injunctive relief are proper pursuant to 28 U.S.C. § 2201 (declaratory judgment) and 5 U.S.C. § 702 (Administrative Procedures Act).

4.

Venue is proper in this court pursuant to 28 U.S.C. § 1391(e), 28 U.S.C. § 1402(a)(1), and United States District Court for the District of Oregon Local Rule 3.4.

Parties

5.

Plaintiff Oregon Medical Association (hereinafter "OMA") is a private association of physicians organized for the purpose of promoting professionalism, education, quality of care, and loss prevention among Oregon's medical community. Enforcement of CMS's Interpretative Guideline as to required content of "informed consent" will directly impact the physician members of the OMA, and the OMA itself in its educational endeavors.

6.

Plaintiff Anton K. Broms, MD, is a physician licensed to practice medicine in the State of Oregon. Dr. Broms' primary place of business is located in Tualatin, Oregon. Dr. Broms holds clinical privileges at Legacy Meridian Park located in Tualatin, Oregon, and could lose his Hospital privileges if the Hospital is required to document informed consent as required by the new guidelines which are contrary to ORS 677.097.

7.

Plaintiff Stewart M. Wilson, Jr., MD, is a physician licensed to practice medicine in the State of Oregon. Dr. Wilson's primary place of business is located in Roseburg, Oregon. Dr. Wilson holds clinical privileges at Mercy Medical Center and the local surgicenter located in Roseburg, Oregon, and could lose his Hospital privileges if the Hospital is required to document informed consent as required by the new guidelines which are contrary to ORS 677.097.

8.

The United States of America is a sovereign nation, responsible for enacting, implementing, and enforcing the Social Security Act (hereinafter "SSA") and regulations purportedly adopted under the authority of that Act. The United States Department of Health and Human Services ("HHS") and the Centers for Medicare and Medicaid Services ("CMS") are agencies of the United States that have the responsibility for implementing and enforcing provisions of the SSA.

9.

Defendant Michael O. Leavitt ("Leavitt") is the Secretary of Health and Human Services of the United States and is sued in his official capacity. Defendant Leslie V. Norwalk is the

Acting Administrator of CMS and is sued in hers official capacity.

Oregon's Patient Informed Consent Law

10.

Oregon's patient informed consent law was enacted by the Oregon legislature in 1977, and has been codified as ORS 677.097. The law was amended in 1983 as provided in Oregon Laws, Chapter 486, section 8. ORS 677.097 provides as follows:

> (1) In order to obtain the informed consent of a patient, a physician or podiatric physician and surgeon shall explain the following:
> (a) In general terms the procedure or treatment to be undertaken;
>
> (b) That there may be alternative procedures or methods of treatment, if any; and
>
> (c) That there are risks, if any, to the procedure or treatment.
>
> (2) After giving the explanation specified in subsection (1) of this section, the physician or podiatric physician and surgeon shall ask the patient if the patient wants a more detailed explanation. If the patient requests further explanation, the physician or podiatric physician and surgeon shall disclose in substantial detail the procedure, the viable alternatives and the material risks unless to do so would be materially detrimental to the patient. In determining that further explanation would be materially detrimental the physician or podiatric physician and surgeon shall give due consideration to the standards of practice of reasonable medical or podiatric practitioners in the same or a similar community under the same or similar circumstances.

11.

ORS 677.097 establishes the process and procedure for a physician to obtain informed consent of a patient in Oregon. In order to obtain informed consent, Oregon physicians are required to explain in general terms the medical procedure or treatment to be undertaken; that there may be alternative procedures or methods of treatment, if any; and that there are risks, if any, in the procedure or treatment. After giving this general information the physician must ask

the patient if the patient wants a more detailed explanation. If the patient requests further detail the physician shall disclose in substantial detail the procedure, the viable alternatives and the material risks unless it would be materially detrimental to the patient in accordance with the recognized standard of practice.

12.

A revised interpretive guideline issued by CMS on April 13, 2007, purports to clarify 42 C.F.R. §482.24(c)(2)(v) by setting forth a list of minimum elements that must be met to constitute patient informed consent for medical treatment or surgical procedure. The SSA, and its implementing regulations, do not define for medical purposes what constitutes patient informed consent. Traditionally, that determination has been left to each State. The CMS guideline eliminates patient choice and requires additional statements not required by Oregon law.

13.

Oregon law requires that physicians obtain a patient's informed consent before providing or conducting medical treatment and/or surgical procedures. Oregon's legislature has proscribed through legislative enactment the requirements for obtaining patient "informed consent." ORS 677.097. CMS's interpretation of the definition of "informed consent" is contrary to Oregon law as it removes patient choice as to what patients may want to know.

14.

By interpreting the definition of what constitutes patient "informed consent" in a manner contrary to Oregon law, CMS is attempting to exercise supervision and control over hospitals and

the practice of medicine and the manner in which healthcare is provided in Oregon. The SSA, codified at 42 U.S.C. § 1395, specifically provides:

> Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.

The SSA prohibits HHS, CMS, or any other Federal agency from exercising any supervision or control over the practice of medicine or manner in which medicine is provided in Oregon or any other State. By requiring hospitals to have documentation of what constitutes informed consent CMS is exercising supervision and control over what physicians must tell their patients. Oregon has a law which governs informed consent and yet CMS's revised Interpretive Guidelines seek to override Oregon law. CMS's revised Interpretive Guideline §482.24(c)(2)(v) provides as follows:

> ## A-0238 Medical Records
>
> **§482.24(c)(2)(v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent. Interpretive Guidelines §482.24(c)(2)(v)**
>
> *Informed consent is discussed in three locations in the CMS Hospital Conditions of Participation. See also the guidelines for 482.13(b)(2) pertaining to patients' rights, and the guidelines for 482.24(c)(2)(v), pertaining to surgical services. The medical record must contain a document recording the patient's informed consent for those procedures and treatments that have been specified as requiring informed consent. Medical staff by-laws should address which procedures and treatments require written informed consent. There may also be applicable Federal or State law requiring informed consent. The informed consent form contained in the medical record should provide evidence that it was properly executed.*
>
> ***Informed Consent Forms***

A properly executed informed consent form should reflect the patient consent process. Except as specified for emergency situations in the hospital's informed consent policies, all inpatient and outpatient medical records must contain a properly executed informed consent form prior to conducting any procedure or other type of treatment that requires informed consent. An informed consent form, in order to be properly executed, must be consistent with hospital policies as well as applicable State and Federal law or regulation. A properly executed informed consent form contains the following minimum elements:

- *Name of the hospital where the procedure or other type of medical treatment is to take place;*
- *Name of the specific procedure, or other type of medical treatment for which consent is being given;*
- *Name of the responsible practitioner who is performing the procedure or administering the medical treatment;*
- *Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient's legal representative; (Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity. Hospitals are free to delegate to the responsible practitioner, who uses the available clinical evidence as informed by the practitioner's professional judgment, the determination of which material risks, benefits and alternatives will be discussed with the patient.)*
- *Signature of the patient or the patient's legal representative; and*
- *Date and time the informed consent form is signed by the patient or the patient's legal representative. If there is applicable State law governing the content of the informed consent form, then the hospital's form must comply with those requirements. A well-designed informed consent form might also include the following additional information:*
- *Name of the practitioner who conducted the informed consent discussion with the patient or the patient's representative.*
- *Date, time, and signature of the person witnessing the patient or the patient's legal representative signing the consent form.*
- *Indication or listing of the material risks of the procedure or treatment that were discussed with the patient or the patient's representative;*
- *Statement, if applicable, that physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital's policies and, in the case of residents, based on their skill set and under the supervision of the responsible practitioner.*
- *Statement, if applicable, that qualified medical practitioners who are not physicians who will perform important parts of the surgery or administration of anesthesia will be performing only tasks that are within their scope of practice, as determined under State law and regulation, and for which they have been granted privileges by the hospital.*

This interpretive guideline purports to clarify 42 C.F.R. §482.24(c)(2)(v) which provides: "[p]roperly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent." CMS's own administrative regulation, 42 C.F.R. §482.24(c)(2)(v), recognizes that informed consent is proper if it is obtained in accordance with State law.

15.

As a result of Defendants' interpretation of 42 C.F.R. §482.24(c)(2)(v) as provided in CMS's revised Interpretive Guideline §482.24(c)(2)(v), effective April 13, 2007, Oregon physicians who obtain patient informed consent for medical treatment or surgical procedures in conformance with Oregon law are subject to disciplinary proceedings by healthcare facilities resulting in revocation of physician clinical privileges; and reporting to the National Practitioners Data Bank.

16.

Legacy Health System hospitals are healthcare facilities organized as an Oregon not for profit corporation. Legacy Meridian Park Hospital is a part of the Legacy Health System. Legacy Meridian Park Hospital participates in the Medicare and Medicaid programs. Legacy Meridian Park Hospital's participation in the Medicare and Medicaid programs is subject to the provisions of the SSA and the administrative regulations adopted to implement the Medicare and Medicaid programs created by the SSA.

17.

As the result of a prior audit conducted under the former interpretive guideline by the

Oregon Department of Human Services, on behalf of CMS, the Legacy Health System hospitals had been notified by CMS, that unless they require physicians to document informed consent as prescribed by CMS's interpretive guidelines, the Legacy Health System hospitals will be terminated from the Medicare and Medicaid programs. CMS's revised Interpretive Guideline §482.24(c)(2)(v) still requires that Legacy Health System comply with CMS's minimum elements for informed consent.

18.

Plaintiff Broms, MD, and other physicians with clinical privileges at Legacy Health System hospitals have been told by the administrative department of Legacy Health System that they must comply with CMS's interpretative guidelines defining patient "informed consent" for all medical treatment or surgical procedures performed or delivered to patients at Legacy Health System hospitals or else their clinical privileges will be revoked. This statement to the physician by the Hospital was under the old rule, but the new rule requires minimum disclosures in violation of ORS 677.097 and overlooks patient choice.

19.

Mercy Medical Center is a healthcare facility organized as an Oregon not for profit corporation. Mercy Medical Center participates in the Medicare and Medicaid programs. Mercy Medical Center's participation in the Medicare and Medicaid programs is subject to the provisions of the SSA and the administrative regulations adopted to implement the Medicare and Medicaid programs created by the SSA.

20.

As the result of an audit conducted by the Oregon Department of Human Services, on behalf of CMS, Mercy Medical Center has been notified by CMS, that unless it requires physicians to document informed consent as prescribed by CMS's interpretive guidelines, Mercy Medical Center will be terminated from the Medicare and Medicaid programs. CMS's revised Interpretive Guideline §482.24(c)(2)(v) still requires that Mercy Medical Center comply with CMS's minimum elements for informed consent.

21.

Plaintiff Wilson, MD, and other physicians with clinical privilege at Mercy Medical Center have been told by the administrative department of Mercy Medical Center that they must comply with CMS's interpretative guideline defining patient "informed consent" for all medical treatment or surgical procedures performed or delivered to patients at Mercy Medical Center. This statement to the physician by the Hospital was under the old rule, but the new rule requires minimum disclosures in violation of ORS 677.097 and overlooks patient choice

Claim for Relief
(Declaratory Judgment and Injunctive Relief)

22.

Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-20 above.

23.

Plaintiffs contend that CMS's revised interpretive guideline defining patient "informed consent" as that term is used in 42 C.F.R. §482.24(c)(2)(v) violates the rule making requirements

of the Administrative Procedures Act (APA), 5 U.S.C. § 553; violates the rule making requirement of 42 U.S.C. §1395hh; violates the express prohibition that no Federal officer or employee may exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, 42 U.S.C. § 1395; and violates the Tenth Amendment of the United States Constitution by usurping powers the Constitution denies to Congress and reserves to the states or the people.

24.

Defendants contend that revised the Interpretative Guideline §482.24(c)(2)(v) and its enforcement is valid and permissible, and are enforcing it.

25.

Plaintiffs have a present need to know whether the revised Interpretative Guideline §482.24(c)(2)(v) and its enforcement is valid.

26.

There is a present justiciable controversy between the parties as to whether the revised Interpretative Guideline §482.24(c)(2)(v) and its enforcement is valid. Declaratory relief is appropriate to resolve this controversy.

27.

Plaintiffs ask this court to declare that the revised Interpretative Guideline §482.24(c)(2)(v) and its enforcement violates the SSA; the APA; and the United States Constitution.

28.

Plaintiffs ask this court to preliminarily and permanently enjoin Defendants from enforcing or otherwise giving effect to the revised Interpretative Guideline §482.24(c)(2)(v).

29.

Pursuant to 28 U.S.C. §§ 1920 and 2412 (a)(1), Plaintiffs are entitled to recover their costs of suit. Pursuant to 28 U.S.C. § 2412(b) and (d)(1)(A), Plaintiffs are entitled to recover reasonable attorney fees incurred in connection with this litigation.

WHEREFORE, Plaintiffs request entry of judgment in their favor as follows:

1. Declaring the revised Interpretative Guideline §482.24(c)(2)(v) invalid;

2. Declaring enforcement of the revised Interpretative Guideline §482.24(c)(2)(v) exceeds the authority of Defendants or is unconstitutional;

3. Awarding Plaintiffs their reasonable attorney fees and costs of suit; and

4. Awarding Plaintiffs such other relief as the court deems equitable and just.

DATED this 27th day of August, 2007.

/s/ DAVID J. MADIGAN

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document was filed electronically on August 27, 2007, and that the electronic filing of this document constitutes service on the following:

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